510(k) Summary

FEB 2 8 2013

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Device Information

Trade Name:	Galaxy (ACIF, PLIF, TLIF and ALIF) Peek cage
Common Name:	Intervertebral Body Fusion Device, IBF Device
Classification Name:	Intervertebral Body fusion Device, Cervical Intervertebral Body fusion Device, Lumbar
Product Code:	ODP, MAX
Regulation Number:	888.3080
Date prepared:	12/17/2012

General Description

The Galaxy (ACIF, PLIF, TLIF and ALIF) Peek cage device consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. And consist of:

1) Cervical interbody fusion Device (Galaxy ACIF cage), which may be implanted as a single device via an anterior approach.

2) Lumbar Interbody Fusion Device (Galaxy PLIF, TLIF and ALIF), which may be implanted.

- Bilaterally via a posterior(PLIF) approach;
- As a single device via a transforaminal(TLIF) approach;
- As a Single device via Anterior (ALIF) approach.

The implants are made of polyether-ether-ketone (PEEK-OPTIMA LT1) body with the x-ray markers made of Titanium alloy (Ti-6Al-4V).

The Galaxy (ACIF, PLIF, TLIF and ALIF) Peek cage is implanted by using the instruments manufactured from stainless steel materials that conform to ASTM F899.

Indication for Use

The Galaxy (ACIF) Peek Cage is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Galaxy (PLIF, TLIF, and ALIF) Cage is indicated for intervertebral body fusion of the lumbar spine from L2-S1 in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level or two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Materials:

The implants are made of polyether-ether-ketone (PEEK-OPTIMA LT1) body with the x-ray markers made of Titanium alloy (Ti-6A1-4V). The intended use, technological characteristics, mode of action and materials of construction are the same as those of the referenced predicate devices.

Performance Data:

The Galaxy (ACIF, PLIF, TLIF and ALIF) Peek Cage devices were tested according to the ASTM 2077, specifically, Static and Dynamic Axial CompressionTesting, Static and Dynamic Torsion Testing and Static Subsidence testing under Axial Compression, per ASTM 2267.

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

*BM KOREA Co. Ltd., SYNSTER Cage (K111820)

Comparison to Predicate Devices:

The Substantial equivalence of this device is based on equivalence in intended use, material, designs, and operational principles to the predicate device, BM KOREACo.Ltd, SYNSTER cage (K111820)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

DIO Medical Co., LTD.
% Kodent Incorporated
Ms. April Lee
Consultant
325 North Puente Street, Unit B
Brea, California 92821

Re: K122872
Trade/Device Name: Galaxy (ACIF, PLIF, TLIF, and ALIF) Peek Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: February 15, 2013
Received: February 25, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K122872

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Prescription Use _____x_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices